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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/578,848	07/24/2006	Ulla Hellstrom	620-438	5041

23117 7590 01/25/2011

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EXAMINER	
KINSEY WHITE, NICOLE ERIN	
ART UNIT	PAPER NUMBER
1648	
MAIL DATE	DELIVERY MODE
01/25/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/578,848	HELLSTROM ET AL.	
	Examiner	Art Unit	
	NICOLE KINSEY WHITE	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 January 2011*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4-12,20 and 22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4-12,20 and 22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Withdrawn Rejections

The rejection of claims 1, 4-12, 20 and 22 under 35 U.S.C. 103(a) as being unpatentable over Neurath et al. (EP 154902A) and further in view of Zavaglia et al. (Italian Journal of Gastroenterology, 1996, 28(6):324-331, Abstract only) and Wei et al. (World J Gastroenterol, 2002;8(2):276-281) has been withdrawn in view of applicant's arguments.

The rejection of claims 1, 4-12, 20 and 22 under 35 U.S.C. 103(a) as being unpatentable over Neurath et al. (EP 448126A) and further in view of Zavaglia et al. (Italian Journal of Gastroenterology, 1996, 28(6):324-331, Abstract only) and Wei et al. (World J Gastroenterol, 2002;8(2):276-281) has been withdrawn in view of applicant's arguments.

The rejection of claims 1, 4-12, 20 and 22 under 35 U.S.C. 103(a) as being unpatentable over Neurath et al. (U.S. Patent No. 4,847,080) and further in view of Zavaglia et al. (Italian Journal of Gastroenterology, 1996, 28(6):324-331, Abstract only) and Wei et al. (World J Gastroenterol, 2002;8(2):276-281) has been withdrawn in view of applicant's arguments.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 4-12, 20 and 22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Enablement is considered in view of the Wands factors (MPEP 2164.01(a)).

The claims are directed to a method of determining whether an individual having hepatitis B virus (HBV) infection will respond to interferon alpha (IFN-a) treatment, the method comprising: i) obtaining a pre-treatment sample from said HBV-infected individual, and ii) analyzing said pre-treatment sample for the presence or absence of antibodies reactive with a preS1 peptide consisting of the sequence of residues 94-117 (SEQ ID NO: 1) wherein the presence of said antibodies in said pre-treatment sample indicates that said individual will respond to said treatment and the absence of said antibodies in said pre-treatment sample indicates that said individual will not respond to said treatment.

The prior art teaches that HBV infected individuals with preS1 antibodies will recover from HBV infection. For example, Wei et al. (World J Gastroenterol, 2002;8(2):276-281) teaches that the appearance of anti-preS1 antibody in the course of most acute hepatitis patients predicts the clearance of HBeAg and disappearance of preS1 dominants and HBV-DNA followed by elimination of HBsAg and seroconversion to anti-HBs. The role of anti-preS1 antibodies might be neutralization of HBsAg with preS1-coded epitopes (particularly infective HBV virions), as the antibodies were found in most cases of acute hepatitis followed by recovery. Anti-preS1 antibodies were hardly observed in patients with acute hepatitis progressing to chronic disease and in chronic hepatitis patients with continuing presence of preS1 domain and seropositive of HBeAg or anti-HBe. But anti-preS1 antibodies were detected in a few patients with chronic aggressive hepatitis undergoing treatment with antiviral agents, and the appearance of the antibodies correlated well with healthy improvement. The apparent prognostic implications of anti-preS1 antibodies are of interest in screening for this marker in hepatitis B patients. In conclusion, the presence of antibodies against preS1 in serum during acute infection may indicate subsequent recovery. Through detection of anti-preS1 antibodies based on biotin-labeled protein A indirect ELISA and follow-up study, it affords some information about the state and future prognosis of hepatitis B patients. The detection system has potential to be developed to a new kit for diagnosis and prognosis of hepatitis B patients (see page 280).

Wei et al. used the 21-119 region of preS1 because it contains several known epitopes of HBV (27-35aa, 72-78aa, 32-47aa, 41-53aa, 94-105aa, 106-117aa, 12-21aa, 21-30aa, 29-48aa and 94-117aa) (see page 276 of Wei et al.).

Neither the claims or specification defines what is meant by ”respond to said treatment" such that one of ordinary skill in the art could practice the claimed method and distinguish between recovery (as taught by the prior art) and an actual response to IFN-α treatment (as claimed). The specification states on page 4 that “an individual who is responsive to IFN treatment (i.e. a responder) may, in response to IFN treatment, show an improvement in one or more symptoms of HBV infection. For example, the level of one or more biomarkers associated with HBV infection, such as serum HBeAg levels, may be reduced or eliminated by IFN treatment of an individual who is responsive to the treatment.” However, an HBV infected individual who is recovering from HBV would also display these same improvements (see teachings of Wei et al. above). Thus, in view of the prior art, one of ordinary skill in the art practicing the claimed method would not know if an individual recovered or responded to treatment.

Given the teachings of the prior art and the lack of guidance in the specification, it would require undue experimentation for one skilled in the art to practice the claimed method.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NICOLE KINSEY WHITE whose telephone number is (571)272-9943. The examiner can normally be reached on Monday through Friday from 9:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Zachariah Lucas can be reached on (571) 272-0905. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nicole Kinsey White/
Examiner, Art Unit 1648

/Stacy B Chen/
Primary Examiner, Art Unit 1648